FTC Expands Scope of Hart-Scott-Rodino Rules for Pharmaceutical Licenses

The Federal Trade Commission adopted new rules that will expand the number of pharmaceutical licensing transactions that are subject to Hart-Scott-Rodino filings and review by the FTC or Department of Justice. The new rules apply to licenses involving the transfer of exclusive rights to a pharmaceutical patent or part of patent.

Historically, the FTC has deemed a licensing agreement in which the patent holder conveys exclusive rights to a licensee – but retains manufacturing rights under its patents – not to constitute a transfer of assets that triggers obligations under the HSR Act. While that remains the case generally, the new rules single out pharmaceutical licensing for special treatment, and provide that a pharmaceutical patent license will constitute an asset acquisition if it transfers "all commercially significant rights" to a patent within a therapeutic area (or for a specific indication within a therapeutic area). Such licensing arrangements will be reportable under the HSR Act (assuming all requisite size tests are met), even if the licensor retains manufacturing or other similar rights.

The FTC has introduced another rule – also limited to pharmaceutical licensing – defining "co-rights" such as co-development, co-promotion, co-marketing and co-commercialization arrangements that do not include the right of a licensor to use a patent or part of a patent. The FTC's new rules reflect the FTC's long-standing position that exclusive licenses in which the licensor retains traditional co-rights are asset acquisitions and are potentially reportable under the HSR Act. In addition, the FTC's position continues to be that agreements that merely convey distribution rights will not constitute asset acquisitions, and hence these arrangements will not be reportable.

As noted above, the new rules will apply only to pharmaceutical licensing. The rules will apply to patents covering products whose manufacture and sale would produce revenue in the following areas: medical and botanical manufacturing, pharmaceutical preparation manufacturing, in-vitro diagnostic substance manufacturing and biological product (except diagnostic) manufacturing. It is very likely that the implementation of these new rules will result in an increased number of HSR filings for pharmaceutical licensing transactions.

The propriety of industry-specific filing requirements was called into question when the rules were proposed, based on the fact that the HSR Act contains no provision authorizing such an approach. In addition, many in the industry have questioned whether the FTC had developed a sufficient empirical basis for some of the predicate assumptions on which the rules appear to have been justified. It remains to be seen whether, now that the rules have been adopted, they will face a challenge.

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